



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q96589

Hiroshi SUGIYAMA, et al.

Appln. No.: 10/598,789

Group Art Unit: Unknown

Confirmation No.: 1416

Examiner: Unknown

Filed: September 12, 2006

For:

NOVEL INDOLE DERIVATIVE FOR ALKYLATING SPECIFIC BASE SEQUENCE OF DNA

AND ALKYLATING AGENT AND DRUG CONTAINING THE DERIVATIVE

<u>INFORMATION DISCLOSURE STATEMENT</u> <u>UNDER 37 C.F.R. §§ 1.97 and 1.98</u>

MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

- 1. J.M. Turner, et al. "Recognition of Seven Base Pair Sequences in the Minor Groove of DNA by Ten-Ring Pyrrole-Imidazole Polyamide Hairpins", J. Am. Chem. Soc., (1997), 119, pp. 7636-7644 with Abstract.
- 2. R. Clairac, et al. "NMR Characterization of Hairpin Polyamide Complexes with the Minor Groove of DNA", Journal of the American Chemical Society, Vol. 119, No. 34, August 27, 1997 with Abstract.
- 3. A. Chang, et al. "Strand Selective Cleavage of DNA by Diastereomjers of Hairpin Polyamide-seco-CBI Conjugates", J. Am. Chem. Soc., (2000), 122, pp. 4856-4864 with Abstract.

INFORMATION DISCLOSURE STATEMENT

U.S. Appln. No.: 10/598,789

- 4. Z. Tao, et al. "Rational Design of Sequences-Specific DNA Alkylating Agents Based on Duocarmycin A and Pyrrole- Imidazole Hairpin Polyamides", J. Am. Chem. Soc., (1999), 121, pp. 4961-4967 with Abstract.
- 5. Z. Tao, et al. "Highly Cooperative DNA Dialkylation by the Homodimer of Imidazole-Pyrrole Diamide-CPI Conjugate with Vinyl Linker", J. Am. Chem. Soc., (2000), 122, pp. 1602-1608 with Abstract.
- 6. T. Bando, et al. "Molecular Design of a Pyrrole-Imidazole Hairpin Polyamides for Effective DNA Alkylation", Chem.Eur. J., (2002), 8, No. 20, pp. 4781-4790 with Abstract.
- 7. D. Boger, et al. "An Improved Synthesis of 1,2,9,9a-Tetrahydrocyclopropa[c]benz[e]indol-4-one (CBI): A Simplified Analogue of the CC-1065 Alkylation Subunit", J. Org. Chem., (1992), 57, pp. 2873-2876.
- 8. D. Boger, et al. "An Efficient Synthesis of 1,2,9,9a-Tetrahydrocyclopropa[c]benz[e]indol-4-one (CBI): An Enhanced and Simplified Analog of the CC-1065 and Duocarmycin Alkylation Subunits", J. Org. Chem., (1995), 60, pp. 1271-1275.
- 9. D. Boger, et al. "Synthesis of *N*-(*tert*-Butyloxycarbonyl)-CBI, CBI, CBI-CDPI₁, and CBI-CDPI₂: Enhanced Functional Analogues of CC-1065 Incorporating the 1,2,9,9a-Tetrahydrocyclopropa[*c*]benz[*e*]indol-4-one (CBI) Left-Hand Subunit", J. Org. Chem., (1990), 55, pp. 5823-5832.

One copy of each of the listed documents is submitted herewith.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

INFORMATION DISCLOSURE STATEMENT

U.S. Appln. No.: 10/598,789

The submission of the listed documents is not intended as an admission that any such document

constitutes prior art against the claims of the present application. Applicant does not waive any right to

take any action that would be appropriate to antedate or otherwise remove any listed document as a

competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and

the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said

Deposit Account.

Respectfully submitted,

Registration No. 32,607

SUGHRUE MION, PLLC

Telephone: (202) 293-7060

Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: January 5, 2007

3

Substitute for Form	f f t		Сотр	olete if Known
		IDE	Application Number	10/598,789
INF	ORMATION DISC	CLOSURE TO THE	Confirmation Number	1416
TS	ATEMENT BY AP	PLICANT	Filing Date	September 12, 2006
517	ALEMENT DI AL	JAN 0 5 2007	First Named Inventor	Hiroshi SUGIYAMA
	(use as many sheets as n	necessary)	SArt Unit	Unknown
		13	Examiner Name	Unknown
Sheet	1	of 2	Attorney Docket Number	Q96589
· · · · · · · · · · · · · · · · · · ·				

			U.S. 1	PATENT DOCUM	MENTS
Examiner	Cite	Document	Number	Publication Date	
Initials*	No.1	Number	Kind Code ² (if known)	MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US			
		US			

			F	OREIGN PA	TENT DOCUM	ENTS	
Examiner	Cite	Fo	reign Patent Docun	ient	Publication Date	Name of Patentee or	
Initials*	No.1	Country Code ³	Number ⁴	Kind Code ⁵ (if known)	MM-DD-YYYY	Applicant of Cited Document	Translation ⁶

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation ⁶
		J.M. Turner, et al. "Recognition of Seven Base Pair Sequences in the Minor Groove of	ĺ
		DNA by Ten-Ring Pyrrole-Imidazole Polyamide Hairpins", J. Am. Chem. Soc., (1997),	
		119, pp. 7636-7644 with Abstract.	
		R. Clairac, et al. "NMR Characterization of Hairpin Polyamide Complexes with the	
i		Minor Groove of DNA", Journal of the American Chemical Society, Vol. 119, No. 34,	ł
		August 27, 1997 with Abstract.	
		A. Chang, et al. "Strand Selective Cleavage of DNA by Diastereomjers of Hairpin	1
		Polyamide-seco-CBI Conjugates", J. Am. Chem. Soc., (2000), 122, pp. 4856-4864 with	
		Abstract.	
		Z. Tao, et al. "Rational Design of Sequences-Specific DNA Alkylating Agents Based	
		on Duocarmycin A and Pyrrole- Imidazole Hairpin Polyamides", J. Am. Chem. Soc.,	
		(1999), 121, pp. 4961-4967 with Abstract.	
		Z. Tao, et al. "Highly Cooperative DNA Dialkylation by the Homodimer of Imidazole-	
		Pyrrole Diamide-CPI Conjugate with Vinyl Linker", J. Am. Chem. Soc., (2000), 122,	
		pp. 1602-1608 with Abstract.	
		T. Bando, et al. "Molecular Design of a Pyrrole-Imidazole Hairpin Polyamides for	
		Effective DNA Alkylation", Chem.Eur. J., (2002), 8, No. 20, pp. 4781-4790 with	
		Abstract.	
		D. Boger, et al. "An Improved Synthesis of 1,2,9,9a-	
		Tetrahydrocyclopropa[c]benz[e]indol-4-one (CBI): A Simplified Analogue of the CC-	
		1065 Alkylation Subunit", J. Org. Chem., (1992), 57, pp. 2873-2876.	

		1
1	n . a	•
Examiner Signature	Date Considered	1

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or follow the hyperlink from the title of the document to the intranet. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to indicate here if English language Translation is attached.

ubstitute for Form 144	0 A & D/DTO			Сотр	olete if Known
				Application Number	10/598,789
INFOI	RMATION	DISCLOSURE	2	Confirmation Number	1416
STAT	EMENT D	Y APPLICANT	40	Filing Date	September 12, 2006
SIAI	EMENI D	I AFFLICANI		First Named Inventor	Hiroshi SUGIYAMA
(use	as many shee	ts as necessary) JAN 05	יטטו	Art Unit	Unknown
		12	a di	Examiner Name	Unknown
Sheet	2	of 2	\$	Attorney Docket Number	Q96589

			U.S. I	PATENT DOCUME	INTS
Examiner	Cite	Document l	Number	Publication Date	
Initials*	No.1	Number	Kind Code ² (if known)	MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US			

			F	OREIGN PA	TENT DOCUMEN	ITS	
Examiner	Cite	Fore	eign Patent Docu	ment	Publication Date	Name of Patentee or	
Initials*	No.1	Country Code ³	Number ⁴	Kind Code ⁵ (if known)	MM-DD-YYYY	Applicant of Cited Document	Translation ⁶
1							
							
					-		
		<u> </u>					

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation ⁶
		D. Boger, et al. "An Efficient Synthesis of 1,2,9,9a-	
		Tetrahydrocyclopropa[c]benz[e]indol-4-one (CBI): An Enhanced and Simplified	
		Analog of the CC-1065 and Duocarmycin Alkylation Subunits", J. Org. Chem., (1995), 60, pp. 1271-1275.	
		D. Boger, et al. "Synthesis of <i>N</i> -(<i>tert</i> -Butyloxycarbonyl)-CBI, CBI, CBI-CDPI ₁ , and CBI-CDPI ₂ : Enhanced Functional Analogues of CC-1065 Incorporating the 1,2,9,9a-Tetrahydrocyclopropa[c]benz[e]indol-4-one (CBI) Left-Hand Subunit", J. Org. Chem., (1990), 55, pp. 5823-5832.	

Farming State 4		
Examiner Signature	Date Conside	ered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or follow the hyperlink from the title of the document to the intranet. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to indicate here if English language Translation is attached.